ROC™ Lumbar Plating System
510(k) SUMMARY
January 2005

FEB 18 2005

K050078

I. **Company**: Alphatec Manufacturing Inc.
6110 Corte Del Cedro
Carlsbad, CA 92009, USA
(760) 431-9286

II **Contact Person**: Ellen Yarnall, Director of Regulatory Affairs

III **Trade/Proprietary Name**: ROC™ Lumbar Plating System

IV **Product Description**:

The ROC™ Lumbar Plating System is a spinal fixation system intended to improve stability of the lumbosacral spine. There are a variety of implants that can be used for this procedure including; lumbar plates, bolts, offset links and locking nuts. All components are made from titanium alloy, Ti 6Al 4V meeting specifications of ASTM F136.

V. **Classification**

MNI (21 CFR 888.3070)	Orthosis, Spinal Pedicle Fixation
MNH (21 CFR 888.3070)	Orthosis, Spondyloisthesis Spinal Fixation

VI **Indications for Use**

The ROC™ Lumbar Plating when intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the lumbosacral spine: severe spondylolisthesis (grades 3 and 4), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The ROC Lumbar Plating System is indicated for placement in L3 – S1.

VII **Substantial Equivalence**:

The ROC™ Lumbar Plating System is substantially equivalent to other commercially available system such as the TiMX plating system offered by Depuy Spine and the Simmons plating system offered by Smith & Nephew.

VIII **Performance Data**:

Static and dynamic testing of the ROC™ Lumbar Plating System was performed and submitted in this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2005

Ms. Ellen Yarnall
Director of Regulatory Affairs
Alphatec/Nexmed
6110 Corte Del Cedro
Carlsbad, California 92009

Re: K050078
Trade/Device Name: ROC™ Lumbar Plating System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw System
Regulatory Class: II
Product Code: MNH, MNI
Dated: January 10, 2005
Received: January 13, 2005

Dear Ms. Yarnall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

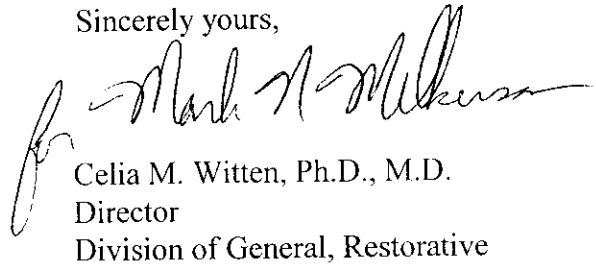
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: ROC™ Lumbar Plating System

Indications for Use:

It is intended that this device, in any system configuration, be removed after the development of solid fusion mass. The ROC™ Lumbar Plating when intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the lumbosacral spine: severe spondylolisthesis (grades 3 and 4), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The ROC Lumbar Plating System is indicated for placement in L3 – S1.

Prescription Use X AND/OR Over-The Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K050078